HOSPIRA, INC. and ORION CORPORATION,

Plaintiffs,

٧.

SANDOZ INTERNATIONAL GmbH, SANDOZ INC., and SANDOZ CANADA INC.,

Defendants.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION No. 3:09-CV-04591 (MLC/TJB)

REDACTED VERSION

MEMORANDUM OF LAW OPPOSING SANDOZ INC.'S MOTION APPEALING THE MAGISTRATE JUDGE'S ORDER REGARDING SANDOZ INC.'S CONTENTIONS

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### TABLE OF CONTENTS

TABLE OF CONTENTS				
TAE	BLE C	OF AUTHORITIES	ii	
I.	INT	RODUCTION	1	
II.	SUM	IMARY OF RELEVANT PROCEEDINGS	1	
III.	SUM	IMARY OF ARGUMENT	4	
IV.	THE MAGISTRATE JUDGE'S DECISION WAS CORRECT BECAUSE SANDOZ US WAS NOT DILIGENT			
	Α.	The Local Patent Rules Require A Showing Of Diligence To Amend Contentions	7	
	B.	Sandoz US Did Not Act Diligently Prior To Serving Its Original Contentions Or After Learning Of Additional References		
	C.	The Magistrate Judge's Decision Correctly Applied The Relevant Law And Is Entitled To Deference	10	
V.	SANDOZ US'S APPEAL OF THE MAGISTRATE JUDGE'S DECISION IS UNTIMELY			
VI.	ALLOWING SANDOZ US TO AMEND ITS CONTENTIONS WOULD CONTRAVENE THE LOCAL PATENT RULES			
VΠ.	CON	ICLUSION	16	

## TABLE OF AUTHORITIES

Cases	Page(s)
CBS Interactive, Inc. v. Etilize, Inc., 257 F.R.D. 195 (N.D. Cal. 2009)	7, 8
Gunter v. Ridgewood Energy Corp., 32 F. Supp. 2d 162 (D.N.J. 1998)	11
King Pharm., Inc. v. Sandoz, Inc., Civil Action No. 08-5974 (GEB/DEA), 2010 U.S. Dist. LEXIS 50163 (D.N.J. May 19, 2010)	7, 8, 13
Major Tours v. Colorel, 720 F. Supp. 2d 587 (D.N.J. 2010)	11
O2 Micro Int'l, Ltd. v. Monolithic Power Sys., 467 F.3d 1355 (Fed. Cir. 2006)	, 13, 14
Phillips v. Greben, No. 04-cv-5590, 2006 WL 3069475 (D.N.J. Oct. 27, 2006)	10, 11
Statutes & Rules	
L. Pat. R. 3.7	4, 7, 14
L. Civ. R. 7.1	12, 13
L, Civ. R. 72.1	10

#### I. INTRODUCTION

The present appeal presents the issue of whether a party can amend its contentions under the Local Patent Rules of this District without needing to show diligence. Defendant Sandoz Inc. ("Sandoz US") should not be rewarded for its own refusal to show diligence. Sandoz US now seeks a ruling from this Court allowing it to rely on new contentions having failed to prove the diligence required by the local rules and the Scheduling Order in this case. Sandoz US's request should be denied.

Because Sandoz US chose not to provide sufficient evidence of diligence after purposefully waiting for months to submit proposed amended contentions, Magistrate Judge Bongiovanni ruled that Sandoz US could not amend its contentions or rely directly on the new contentions of its co-Defendant, Sandoz Canada Inc. ("Sandoz Canada" and, together with Sandoz US, "Defendants").

The Magistrate Judge's decision that Sandoz US could not amend its contentions while choosing not to provide testimony in support of its diligence was correct and is supported by the facts, the law, and the policy behind the local rules. Accordingly, Plaintiffs Hospira, Inc. and Orion Corporation (collectively "Plaintiffs") respectfully ask the Court to affirm Magistrate Judge Bongiovanni's decision.

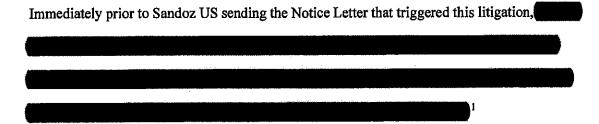
#### II. SUMMARY OF RELEVANT PROCEEDINGS

This patent litigation is subject to the Local Patent Rules for Hatch-Waxman litigation. It involves U.S. Patent Nos. 4,910,214 (the "'214 patent") and 6,716,867 (the "'867 patent") which cover a novel and unique ICU sedative called Precedex.

Defendants seek ANDA approval to manufacture and market a generic version of

Precedex. Sandoz US, filed the ANDA with a

Paragraph IV Certification challenging the validity and infringement of the patents-in-suit.



Pursuant to the local rules and the Court's January 6, 2010 Scheduling Order, Sandoz US served invalidity and non-infringement contentions on December 31, 2009. (D.I. 23, ¶ 1.) To prevent gamesmanship and constant shifting of positions, those contentions could be amended only by order of the Court upon a timely application and showing of good cause, which requires a showing of diligence. (D.I. 23, ¶ 6.)

Eight months after serving its original contentions, in August 2010, Sandoz US served proposed contentions that differed significantly in character and scope from the December 2009 contentions and that injected new issues into the case. In particular, Sandoz US added six documents related to the '867 patent and eleven documents related to the '214 patent. At that same time, Defendant Sandoz Canada served new contentions that mirrored Sandoz US's proposed contentions.

After serving Sandoz US's original contentions in December 2009, defense counsel apparently performed searches and developed analyses in January 2010 that undoubtedly could have been performed a month earlier, before the deadline for serving its December 2009 contentions. Indeed, Sandoz US admitted that its litigation counsel was in possession of all of



the newly added references for months before they tried to amend their contentions to add those references. Inexplicably, after finding what they now contend is case-dispositive prior art, defense counsel sat silent for seven months. During that period, Plaintiffs relied on the December 2009 contentions to focus their case and engaged in a six-month *Markman* process based on those contentions. Days after *Markman* briefing was completed, however, Defendants proposed new and amended contentions. Plaintiffs then moved to preclude Defendants from relying on the new and amended contentions because Defendants had not acted diligently.

With respect to Sandoz Canada, Defendants represented to Magistrate Judge

Bongiovanni that Sandoz Canada was a separate and independent company, and argued therefore
that, as a new party to the case, Sandoz Canada was entitled to submit new contentions.

Plaintiffs argued that Defendants were one company with identical interests and that

the December 2009 contentions necessarily reflected the position of Sandoz Canada. Plaintiffs thus argued that Sandoz Canada should be precluded from serving contentions that differed from the Sandoz US December 2009 contentions. At that time, Plaintiffs had not yet taken discovery on the relationship between Sandoz Canada and Sandoz US.

Magistrate Judge Bongiovanni gave the issue careful consideration, including by holding several teleconferences with the parties and reviewing a full set of briefs. (D.I. 96; D.I. 98; D.I. 109; D.I. 112.) On October 21, 2010, Magistrate Judge Bongiovanni ordered that Sandoz Canada could serve new contentions because it was independent from Sandoz US. (Confidential Certification of Agnes Antonian ("Antonian Cert."), Ex. A, Email from Thomas M. Blewitt to Counsel of Record, Oct. 21, 2010.) The Magistrate Judge further decided that Sandoz US had not provided sufficient evidence of diligence and ordered it to put forth a witness on the issue of

diligence. Sandoz US refused to do so, hiding behind a cloak of privilege. (See D.I. 123.)

During a teleconference on November 16, 2010, the Magistrate Judge offered Sandoz US a second chance to prove diligence by giving it a choice—put forth a witness to testify about diligence, or be limited to making arguments based on res judicata or collateral estoppel after the Court's ultimate ruling on the arguments made by Sandoz Canada in its contentions. Sandoz US again refused to provide a witness, and the Court memorialized Sandoz US's choice in a letter order dated December 16, 2010. (D.I. 138.) Sandoz US then filed the current appeal, in which it continues to refuse to provide additional evidence of diligence.

### III. SUMMARY OF ARGUMENT

Magistrate Judge Bongiovanni's decision that Sandoz US could not amend its contentions if it refused to provide a witness to testify in support of its diligence was based on a thorough review of a comprehensive record of briefing and discussions with the parties. The Magistrate Judge's ruling was correct and supported by the law and the Local Patent Rules of this District because Sandoz US refused to show the necessary diligence required to amend its contentions. Magistrate Judge Bongiovanni has managed this case from the outset, has a thorough knowledge of the proceedings, and her decision is entitled to deference because she did not commit an abuse of discretion.

Magistrate Judge Bongiovanni's ruling is based on the requirement in Local Patent Rule 3.7 that leave to amend contentions may only be granted for good cause, which requires a showing of diligence. Sandoz US indisputably did not prove the diligence required by the rules. In fact, its own briefing and supporting affidavit confirms that Sandoz US waited eight months before it tried to add references of which it knew or should have known when it served its original Notice Letter to Plaintiffs, and certainly when it filed its original contentions. In

addition, Sandoz US concedes that it knew of numerous publicly available prior art references at least seven months before amending its contentions.

Magistrate Judge Bongiovanni gave Sandoz US several chances to submit additional testimony to support its diligence in relation to the filing of its proposed amended contentions, but Sandoz US refused. Sandoz US never provided a full explanation for its delay, except to suggest that its counsel did not realize the relevance of these references until later. Sandoz US cannot use privilege as a sword and a shield—it cannot rely on trial counsel's actions to argue diligence while refusing to allow examination by the Court or Plaintiffs when diligence is called into question. Given that refusal, the Magistrate Judge properly ruled that Sandoz US was not diligent in amending its contentions and, therefore, may not introduce new contentions of its own or rely directly on Sandoz Canada's new contentions.

Sandoz US's motion is also untimely. After reviewing briefs and attorney declarations, Magistrate Judge Bongiovanni issued an order on October 21, 2010 directing Sandoz US to produce a witness on diligence with respect to its proposed contentions. When Sandoz US refused, the Magistrate Judge ordered during a November 16, 2010 teleconference that Sandoz US could either (1) provide a witness to testify with respect to diligence or (2) argue res judicata and collateral estoppel based on the Court's rulings on Sandoz Canada's contentions after the fact. Sandoz US chose again not to provide a witness on diligence, and on December 16 the Court issued a letter order memorializing that choice. However, because Sandoz US did not appeal either the Court's October 21 or November 16 orders, this appeal is not timely and should be rejected.

Finally, allowing Sandoz US to purposefully wait to amend its contentions until after the bulk of the discovery period is past and the *Markman* briefing is complete—without a proper

showing of diligence—would contravene the very essence of the Local Patent Rules. The purpose of the local rules is to require the parties to exercise diligence to crystallize the legal theories, prior art, and claim construction issues early in the case, so that the parties may then conduct focused fact and expert discovery based on those theories. In short, the schedule ordered by the Court must mean something—Plaintiffs are inherently prejudiced by respecting and complying with the Court-ordered schedule while Defendants have consistently acted to delay the progress of this case towards trial.

Sandoz US argues that, because Sandoz Canada was allowed to serve new contentions, Plaintiffs are not prejudiced if Sandoz US can "mirror" those contentions. However, having convinced Magistrate Judge Bongiovanni that Sandoz Canada is a truly independent and unrelated third party entitled to serve new contentions, Defendants should not be able to gain an advantage for Sandoz US beyond what it would be able to assert if Sandoz Canada were a true third party. At most Sandoz US would simply be allowed to assert arguments of *res judicata* and collateral estoppel after the Court ruled on the issues raised in the other party's contentions, as Magistrate Judge Bongiovanni has ruled.

# IV. THE MAGISTRATE JUDGE'S DECISION WAS CORRECT BECAUSE SANDOZ US WAS NOT DILIGENT

Magistrate Judge Bongiovanni's finding that Sandoz US had not shown diligence was correct, and should be given deference. The Local Patent Rules require a party to show good cause to amend contentions, which requires a showing of diligence. The Magistrate Judge's decision that Sandoz US was not diligent in identifying prior art or amending its contentions is well supported by the facts. In short, the Magistrate Judge's decision correctly applied District and Federal Circuit law related to amending contentions. Moreover, the Magistrate Judge did not commit clear error by requiring Sandoz US to provide testimony in support of the conclusory

statements made in its counsel's declaration, or by refusing to allow Sandoz US to amend its contentions, or rely directly on Sandoz Canada's new contentions, when Sandoz US chose not to do so.

## A. The Local Patent Rules Require A Showing Of Diligence To Amend Contentions

Under Local Patent Rule 3.7, "leave to amend invalidity contentions may be granted by order of the Court upon a timely application and showing of good cause." *King Pharms., Inc. v. Sandoz, Inc.*, Civil Action No. 08-5974 (GEB/DEA), 2010 U.S. Dist. LEXIS 50163, at \*10 (D.N.J. May 19, 2010) (internal quotation marks omitted). Establishing good cause "requires a showing of diligence." *O2 Micro Int'l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006). The "burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." *Id.*; *see also CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 201 (N.D. Cal. 2009) ("The party seeking to amend its contentions bears the burden of establishing diligence."). If a moving party fails to show diligence, a court can preclude it from amending its contentions without considering the prejudice to the opposing party. *See O2 Micro*, 467 F.3d at 1368 ("Having concluded that the district court could properly conclude that O2 Micro did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to MPS.").

A party that knew or should have known information but did not timely amend its contentions has not acted with the requisite diligence. See id. at 1367 (holding that a party was not diligent when it "had reason to know" of an infringement theory and "waited almost three

Federal Circuit law applies to this issue because "local patent rules on amendment of infringement contentions are unique to patent cases and have a close relationship to enforcement of substantive patent law." O2 Micro, 467 F.3d at 1364-65.

months... to serve its proposed amended contentions and two more weeks to formally move to amend"); CBS Interactive, 257 F.R.D. at 202 (denying motion to amend where a party was aware of "sufficient details" regarding a technology months before it sought leave to amend its contentions).

Notably, Sandoz US was recently denied the ability to amend its invalidity contentions in another case in this District, when it was aware of a prior art reference when it served its original contentions but did not appreciate the materiality of the reference until months later. *King Pharms.*, 2010 U.S. Dist. LEXIS 50163, at \*12-13.

### B. Sandoz US Did Not Act Diligently Prior To Serving Its Original Contentions Or After Learning Of Additional References

As noted above, Sandoz US has the burden of establishing diligence. See O2 Micro, 467 F.3d at 1366. Sandoz US has failed to meet that burden for at least two reasons: (1) it has not demonstrated that it conducted a diligent search prior to serving it original contentions; and (2) it has not shown that it acted diligently after learning of additional references. Magistrate Judge Bongiovanni recognized that Sandoz US's excuses for its lack of diligence were inadequate and thus refused to allow Sandoz US to amend its contentions.

Sandoz US's new contentions added numerous alleged prior art references related to both patents-in-suit, including six documents related to the '867 patent and eleven documents related to the '214 patent. (See D.I. 98, pp. 9, 13.) Sandoz US admitted that its counsel knew of these references for months prior to including them in Sandoz US's proposed amended invalidity contentions. (See D.I. 95, Mooney Declaration ¶ 26-28) (explaining that Sandoz US's counsel identified seven documents in January 2010 and the rest of the documents by late-April).

Moreover, all of those references should have been known to Sandoz US prior to the submission of its original contentions in December 2009. By that time, as an ANDA filer,

Sandoz US was expected to have exercised reasonable diligence in exploring and developing any invalidity and noninfringement arguments it expected to raise in this litigation. The Local Patent Rules for Hatch-Waxman Litigation place this obligation on defendants because Hatch-Waxman defendants must have duly investigated their defenses prior to filing an ANDA with a Paragraph IV Certification. For example, a reasonably diligent ANDA filer would review the articles that it cited in its own Notice Letter, along with the prior art cited in the references that formed the basis of the Notice Letter. In addition, a reasonably diligent ANDA filer would conduct prior art searches, including keyword searches in publicly available databases of scientific and patent literature. Apparently, Sandoz US's counsel waited until after submitting the Court-ordered December 2009 contentions to take these steps.

A detailed analysis and timeline showing when Sandoz US knew or should have known of each reference was set forth in Plaintiffs' briefs and considered by Magistrate Judge Bongiovanni. (See D.I. 98, pp. 9-15; D.I. 112, pp. 5-8.)

Against this backdrop, Sandoz US argues that its delay of at least seven months to propose amended contentions was appropriate because it waited until "the point in the case where they would cause the least disruption." (Def.'s Br. 11i.)<sup>3</sup> This admittedly purposeful delay simply cannot meet the legal standard for diligence. See O2 Micro, 467 F.3d at 1367. Sandoz US's admission of intentional delay is particularly troubling given that its attorneys also represented Sandoz Canada. In that capacity, they acted to prolong and delay Sandoz Canada's substantive participation in the case by insisting that Sandoz Canada be served through the

References to "Def.'s Br." refer to D.I. 142, the Memorandum of Law In Support Of Sandoz Inc.'s Motion Appealing the Magistrate Judge's December 16, 2010 Letter Order, dated December 29, 2010.

Hague Convention, and by waiting to serve Sandoz Canada's new contentions until a few days after *Markman* briefing had been completed—and three months after Plaintiffs filed the Amended Complaint naming Sandoz Canada—despite telling the Court in May 2010 that they could "ensure that disclosures can be made and claim construction briefing completed by August 6, 2010." (Antonian Cert., Ex. B, Joint Letter to Court, May 4, 2010, at 3.)

In sum, Sandoz US did not act diligently before serving its original contentions in December 2009, after learning of additional references in January 2010, or after identifying purportedly relevant documents produced by Plaintiffs in this case. Sandoz US thus had no good cause to amend its contentions.

# C. The Magistrate Judge's Decision Correctly Applied The Relevant Law And Is Entitled To Deference

Given the facts set forth above, Magistrate Judge Bongiovanni correctly applied the relevant law in holding that Sandoz US could not amend its contentions without showing diligence. The Magistrate Judge held numerous teleconferences with the parties and reviewed a full set of briefing, declarations, and exhibits before deciding that Sandoz US had not satisfied the legal standards set forth above. This Court may overturn that decision only if it is clearly erroneous or contrary to law. See L. Civ. R. 72.1(c)(1)(A); Phillips v. Greben, No. 04-cv-5590, 2006 WL 3069475, at \*3 (D.N.J. Oct. 27, 2006) (upholding Magistrate Judge's denial of plaintiff's motion to amend complaint).

A determination is clearly erroneous when "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Phillips*, 2006 WL 3069475, at \*3 (explaining that a reviewing Court should not reverse a Magistrate Judge's determination just because the Court might have reached a different conclusion) (citation and internal quotation marks omitted). A Magistrate Judge's decision is "contrary to law" when the

Magistrate Judge "has misinterpreted or misapplied applicable law." Gunter v. Ridgewood Energy Corp., 32 F. Supp. 2d 162, 164 (D.N.J. 1998).

Moreover, in areas where a Magistrate Judge is "authorized to exercise his or her discretion, the decision will be reversed only for an abuse of that discretion." *Phillips*, 2006 WL 3069475, at \*4. The abuse of discretion standard is particularly appropriate when "the magistrate judge managed the case from the outset, and thus has a thorough knowledge of the proceedings." *Id.*; *see also Major Tours, Inc. v. Colorel*, 720 F. Supp. 2d 587, 621 (D.N.J. 2010) (upholding Magistrate Judge's denial of discovery request where determination was not "so far afield as to constitute an abuse of discretion, which generally requires a showing that the ruling below rests upon a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact") (citation and internal quotation marks omitted).

Sandoz US has not shown that Magistrate Judge Bongiovanni's decision was clearly erroneous or contrary to the law. To the contrary, the facts described above highlight that Magistrate Judge Bongiovanni provided Sandoz US with ample opportunity to supplement and strengthen its record, but Sandoz US chose not to do so. Thus the facts fully support the Magistrate Judge's finding that Sandoz US did not exercise diligence.

Sandoz US's main complaint is that it would have to reveal privileged information in order to show diligence. However, Magistrate Judge Bongiovanni would have accepted non-privileged evidence if Sandoz US had any to present. (See D.I. 130, Nov. 16, 2010 Tr. 7:18-8:5; 10:13-25.) Sandoz US has known that the parties are operating under the Local Patent Rules since the beginning of this litigation. Sandoz US chose to rely on a declaration by its trial counsel in an attempt to show the diligence required by those rules. If Sandoz US does not have

any non-privileged information to show diligence, then it must be prepared to reveal its privileged information.

In conclusion, Magistrate Judge Bongiovanni's decision is not clearly erroneous or contrary to the law and is entitled to deference. The Local Patent Rules require a showing of diligence, the facts demonstrate that Sandoz US was not diligent, and it was appropriate for her to request additional evidence. Sandoz US cannot put in a declaration that relies solely on the activities of its counsel to show diligence and then refuse the Magistrate Judge's request to speak to that counsel when diligence appears lacking. Sandoz US's attempt to use privilege as a sword and a shield is improper and does not provide good cause for amending its contentions.

## V. SANDOZ US'S APPEAL OF THE MAGISTRATE JUDGE'S DECISION IS UNTIMELY

According to the local rules, a party must appeal a Magistrate Judge's determination of a non-dispositive matter within 14 days after being served with a copy of the Order. L. Civ. R. 7.1. In this case, Magistrate Judge Bongiovanni issued at least two rulings that Sandoz US should have appealed within that 14-day deadline, but it did not. This appeal is thus untimely and should be denied.

The parties first raised this issue with the Court at the end of August 2010 and submitted briefs on September 10 and September 22. Magistrate Judge Bongiovanni issued a first Order on October 21, 2010 by email:

Pursuant to Local Patent Rules 3.3 and 3.6, the Court holds that Sandoz Canada Inc., as a new party, is permitted as of right to serve its invalidity and non-infringement contentions. The Court further holds that a hearing shall be held regarding the issue of Sandoz Inc.'s diligence in filing its preliminary invalidity and non-infringement contentions as well as the instant motion. Sandoz Inc. is required to produce a witness who will testify as to how it was diligent in filing its preliminary invalidity and non-infringement contentions and the instant motion. Plaintiffs will have the opportunity to cross-examine this witness.

(Antonian Cert., Ex. A, Email from Thomas M. Blewitt to Counsel of Record, Oct. 21, 2010 (emphases added).)

Sandoz US recognized this email as an Order in follow-up letters to Magistrate Judge Bongiovanni. (See, e.g., D.I. 123 ("We are writing with respect to Your Honor's October 21, 2010 Order ....").) The deadline to appeal this Order or file and serve a motion for re-argument pursuant to L. Civ. R. 7.1(i) was 14 days. Sandoz US did neither.

Magistrate Judge Bongiovanni's second Order was during the November 16, 2010 teleconference, when she told Sandoz US that it had to make a choice with respect to its proposed contentions—provide evidence of diligence, or rely on *res judicata* and collateral estoppel arguments after the fact. (D.I. 130, Nov. 16, 2010 Tr. 11:1-12.) That teleconference contained an Order by the Magistrate Judge that needed to be appealed within 14 days, but it was not.

In sum, Defendants have had, and missed, at least two previous deadlines to appeal the Magistrate Judge's order that it could not amend its contentions without providing additional evidence of diligence. Accordingly, this appeal is untimely and should be denied.

# VI. ALLOWING SANDOZ US TO AMEND ITS CONTENTIONS WOULD CONTRAVENE THE LOCAL PATENT RULES

Allowing Sandoz US to amend its contentions most of the way through discovery without a proper showing of diligence would contravene the Local Patent Rules, which require the parties to exercise diligence early in the case in order to crystallize the legal theories, prior art, and claim construction issues so that the parties may then conduct focused fact and expert discovery. See King Pharms., 2010 U.S. Dist. LEXIS 50163, at \*10; O2 Micro, 467 F.3d at 1365. Plaintiffs relied on Sandoz US's December 2009 contentions to focus their case and engaged in a six-month Markman process based on those contentions. Days after Markman

briefing was completed, however, Sandoz US proposed new and amended contentions. Plaintiffs are necessarily prejudiced because they have respected and complied with the scheduling orders and Court-ordered deadlines in this case, while Sandoz US has not.

Moreover, because Sandoz US failed to establish diligence, the Court can preclude it from amending its contentions without considering the prejudice to Plaintiffs. *See O2 Micro*, 467 F.3d at 1368 ("Having concluded that the district court could properly conclude that O2 Micro did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to MPS."). The Local Patent Rules allow a party to amend its contentions only if it has shown both diligence and an absence of undue prejudice to the opposing party. L. Pat. R. 3.7(d). If there is no diligence, the presence or absence of prejudice does not have to be considered.

Sandoz US argues that Plaintiffs are not prejudiced by its new contentions because (1) the new contentions raise the same issues that were already in its December 2009 contentions, (2) the newly added references have been in Plaintiffs' files for twenty years, and (3) the new contentions include the same arguments as Sandoz Canada's contentions. (Def.'s Br. 11i-13i.) Sandoz US's arguments are wrong.

First, Sandoz US argues that its new contentions "are based on the same scientific principles and concepts" as its original contentions. (Def.'s Br. 11i.) By that reasoning, Sandoz US would have a full and fair opportunity to present its core arguments under its original contentions, and these new contentions are merely cumulative. However, Sandoz US's new contentions do inject new substantive issues and references into the case, and would require the construction of two additional claim terms. (See D.I. 98, pp. 16-18; D.I. 112, pp. 8-10.) Thus, these new contentions will require a new round of Markman briefing and possibly depositions.

Second, Sandoz US incorrectly argues that Plaintiffs are not prejudiced because they have allegedly known about the new references for up to twenty years. (See Def.'s Br. 1i, 12i.) Even if a prior art article was in one of the Plaintiff's files for twenty years, that does not mean that Plaintiffs were on notice that someone, someday, might make legal arguments based on that reference, including arguments that relate to Markman issues.

Third, Sandoz US argues that, because Sandoz Canada was allowed to serve new contentions, Plaintiffs are not prejudiced if Sandoz US can "mirror" those contentions.

Defendants cannot have it both ways. Having represented that Sandoz Canada is a separate, independent company to convince the Magistrate Judge to allow new contentions for Sandoz Canada, Defendants should not be able to gain an advantage for Sandoz US beyond what it would be able to assert if Sandoz Canada were a true third party, *i.e.*, arguments of *res judicata* and collateral estoppel.

In sum, Sandoz US has not complied with the letter or the spirit of the Local Patent Rules, and Plaintiffs would be prejudiced if Sandoz US is allowed to amend its contentions.

### VII. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court affirm the Magistrate Judge's decision that Sandoz US may not amend its contentions or rely directly on Sandoz Canada's contentions.

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Dated: January 24, 2011

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